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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,277	06/07/2006	Daria Onichtchouk	WEICKM-0051	7320

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EXAMINER
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SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
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1647

NOTIFICATION DATE	DELIVERY MODE
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07/23/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/564,277	<b>Applicant(s)</b> ONICHTCHOUK, DARIA	
	<b>Examiner</b> Christine J. Saoud	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 37-57 and 59-67 is/are pending in the application.
- 4a) Of the above claim(s) 38-40, 42, 43, 47-54, 56, 57, 65 and 66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37, 41, 44-46, 55, 59-64 and 67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 37-57 and 59-67 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 37, 41, 44-46 and 55 have been amended, claims 1-36 and 58 have been canceled and claims 59-67 have been added in the paper filed 25 March 2009. Claims 37-57 and 59-67 are pending in the instant application and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 25 March 2009 have been fully considered but are not deemed persuasive.

### ***Election/Restrictions***

Claims 38-40, 42-43, 48-54 and 56-57 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Newly submitted claims 65-66 and amended claim 47 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the originally claimed invention of claim 47 was directed to use of a protein to make a medicament, which was part of the elected invention of Group I, drawn to a composition comprising DG153 protein, method to make a medicament of DGF153 protein and kits comprising said protein. The newly amended claim 47 and the newly added dependent claims 65-66 are now directed to a method of treating diseases which is directed to a distinct and independent invention

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from that which was originally elected and which would have lacked unity with the elected invention. The invention of Group I was known in the art as evidenced by WO 02/074956, therefore, the composition of DG153 cannot serve as the basis for unity of invention because it does not define a contribution over the prior art. Additionally, 37 CFR 1.475 does not provide for the inclusion of multiple inventions, therefore, if multiple products, processes or manufacture or uses are claimed, the first invention of the category first mentioned in the claims will be considered the main invention and the additional method will lack unity of invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 47 and 65-66 are also withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 38-40, 42-43, 47-54, 56-57 and 65-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 28 July 2008.

Claims 37, 41, 44-46, 55, 59-64, and 67 are under examination in the instant Office action.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Applicant's amendment to the title includes "AND USE THEROF IN THE DIAGNOSIS AND TREATMENT OF PANCREATIC DISEASES, OBESITY AND OTHER METABOLIC DISORDERS". However, the claims are NOT directed to methods of diagnosis and treatment, therefore, the title is not descriptive. The title should be clearly indicative of the invention to which the claims are directed, as well as limited to such. Correction is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 67 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 67 is directed to "a polypeptide", however, this fails to distinguish the claimed invention from material which occurs in nature. In the absence of the hand of man, naturally occurring proteins are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Additionally, mere purity of a naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui, 156 USPQ 426 (1966). However, when purity results in a new utility, patentability is considered. Merck Co. v. Chase Chemical Co., 273 F. Supp. 68 (1967). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment of the claims to recite a purity limitation, if supported by the specification, is suggested to obviate this

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rejection. Applicant should point to the basis in the specification for any amendment to the claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37, 41, 44-46, 55, and 59-64 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. Appl. Pub. 2002/0132978 A1 (Gerber et al) for the reasons of record as applied to claims 37, 41, 44-46 and 58.

Applicant argues at page 12 of the response that Gerber fails to teach or suggest a pharmaceutical composition consisting essentially of the presently claimed polypeptides and a diagnostic or a therapeutic composition comprising such polypeptides because Gerber's protein is longer than the instant DG153 protein of SEQ ID NO:2. Applicant's arguments have been fully considered but are not found persuasive. The protein of Gerber has a leading proline residue, and therefore, differs from the protein of SEQ ID NO:2 by a single amino acid at the N-terminus. However, the protein of Gerber clearly consists essentially of a polypeptide sequence set forth in SEQ ID NO:2 because it contains the entire polypeptide sequence and has a single additional amino acid at the N-terminus, which would be considered by one of ordinary

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skill in the art as “consisting essentially of SEQ ID NO:2” absent evidence to the contrary.

With regard to Applicant’s arguments that Gerber is silent to treatment of pancreatic diseases, metabolic syndrome, metabolic disorders and dysfunctions, or for controlling the function of a gene or gene product that is influenced or modified by said polypeptide, it is again pointed out that recitations of intended use for the claimed compositions do not place any material limitations on the compositions and therefore, the prior art still anticipates the instant claims. Therefore, the claims are anticipated by the prior art of Gerber et al.

Claim 67 is rejected under 35 U.S.C. 102(b) as being anticipated by Golembieski et al. (Accession # S27956 - June 1992).

Golembieski et al. teach a protein which consists of the amino acid sequence of SEQ ID NO:2, as currently claimed. See sequence alignment below. Therefore, the instant claim is anticipated by the prior art.

```
RESULT 1
S27956
arginine-rich protein - human
C;Species: Homo sapiens (man)
C;Date: 17-Apr-1993 #sequence_revision 17-Apr-1993 #text_change 09-Jul-2004
C;Accession: S27956
R;Golembieski, W.; Shridhar, V.; Miller, O.J.; Smith, D.I.
submitted to the EMBL Data Library, June 1992
A;Description: Identification of a new arginine-rich gene from a cosmid containing
clusters of rare restriction sites derived from human chromosomal band 3p21.1.
A;Reference number: S27956
A;Accession: S27956
A;Molecule type: DNA
A;Residues: 1-234 <GOL>
A;Cross-references: UNIPROT:Q86U67; UNIPARC:UPI000015C44A; EMBL:M83751; NID:g178990;
PID:g178991
```

```
Query Match          100.0%; Score 1238; DB 2; Length 234;
Best Local Similarity 100.0%; Pred. No. 1.3e-86;
Matches 234; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
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Qy      1 MGKWHVGGRRGSPRQWGATARGRDLEAVRRGGCGSVGRRRQRRRRRRRRMRMRMRMWATQ 60
      |||
Db      1 MGKWHVGGRRGSPRQWGATARGRDLEAVRRGGCGSVGRRRQRRRRRRRRMRMRMRMWATQ 60
      |||

Qy      61 GLAVRVALSVLPGSRALRPGDCEVCISYLGRFYQDLKDRDVTTFSPATIENELIKFCREAR 120
      |||
Db      61 GLAVRVALSVLPGSRALRPGDCEVCISYLGRFYQDLKDRDVTTFSPATIENELIKFCREAR 120
      |||

Qy      121 GKENRLCYIIGATDDAATKIINEVSKPLAHHIPVEKICEKLKKKDSQICELKYDKQIDLS 180
      |||
Db      121 GKENRLCYIIGATDDAATKIINEVSKPLAHHIPVEKICEKLKKKDSQICELKYDKQIDLS 180
      |||

Qy      181 TVDLKKLRVKELKKILDDWGETCKGCAEKSDYIRKINELMPKYAPKAASAPTDL 234
      |||
Db      181 TVDLKKLRVKELKKILDDWGETCKGCAEKSDYIRKINELMPKYAPKAASAPTDL 234
      |||

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### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/  
Primary Examiner, Art Unit 1647